

## Message Text

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PAGE 01 STATE 085278

64

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06 /054 R

DRAFTED BY DHEW/FDA:JRWEINROTH, M D : AMS

APPROVED BY OES/APT/BMP WJWALSH, III

DHEW/OIH: MACODDING

EUR/EX:JCLARK INFO

EA/ROC: CWFREEMAN INFO

ARA/EX:KDACKERMAN INFO

EA/EX:RSCARRITT INFO

NEA/IRN:BMORTON INFO

----- 120619

P 082317Z APR 76

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES PRIORITY PRIORITY

AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY PORT AU PRINCE PRIORITY

AMEMBASSY TEGUCIGALPA PRIORITY

AMEMBASSY TEHRAN PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY SEOUL PRIORITY

AMEMBASSY BEIRUT PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY PANAMA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY MANILA PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY TAIPEI PRIORITY

AMEMBASSY BANGKOK PRIORITY

AMEMBASSY ANKARA PRIORITY

AMEMBASSY CARACAS PRIORITY

UNCLASSIFIED

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PAGE 02 STATE 085278

UNCLAS STATE 085278

E.O. 11652: N/A

TAGS:TW TH TU OGEN ETRD TBIO AR VE CI, CO, CS, DR, EC, ES,

SUBJECT: FDA ADVISORY - MANDATORY REQUIREMENT FOR  
INSTALLATION OF RELIEF VALVE IN ALL ANESTHESIA MACHINES  
EQUIPPED WITH STANDARD AND SIDE ARM VERNI-TROL VAPORIZERS  
(RECALL T-071-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED: STANDARD AND SIDE ARM VERNI-TROL  
VAPORIZERS - THE STANDARD VERNI-TROL VAPORIZER CAN ONLY  
BE ORDERED AS PART OF AN ANESTHESIA MACHINE, WHILE THE  
SIDE-ARM VERNI-TROL VAPORIZERS MAY BE INSTALLED ON ANY  
ANESTHETIC MACHINE AND ARE IDENTIFIED IN THE FIRM'S  
CATALOG BY TWO STOCK NUMBERS: 216-6356-880, 216-6356-882.

LOT NUMBERS: NO LOT NUMBERS OR MODEL NUMBERS ARE  
ASSOCIATED WITH THESE VAPORIZERS.

MANUFACTURER/RECALLING FIRM:

OHIO MEDICAL PRODUCTS  
DIVISION OF AIRCO, INC.  
3030 AIRCO DRIVE  
MADISON, WISCONSIN 53701

2. REASON FOR ADVISORY: THE FIRM IS MODIFYING ALL  
ANESTHESIA MACHINES WHICH HAVE A VERNI-TROL OR SIDE-ARM  
VERNITROL VAPORIZER BECAUSE FIELD REPORTS AND  
LABORATORY TESTING HAVE INDICATED THAT, UNDER CERTAIN  
CONDITIONS, HIGH PRESSURES IN THE BREATHING CIRCUIT  
CAN CAUSE THE ANESTHETIC AGENT TO BACK UP INTO THE  
FLOW METERS AND THE DELIVERY FLOW LINE TO THE PATIENT  
IN ANESTHESIA MACHINES LACKING A PRESSURE RELIEF VALVE.  
THIS POSSIBILITY REPRESENTS A POSSIBLE OR POTENTIAL  
LIFE THREATENING HAZARD TO THE PATIENT. USERS OF THESE  
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PAGE 03 STATE 085278

VAPORIZERS WERE NOTIFIED BY LETTER DATED FEBRUARY 12, 1976  
AND VALVES AND INSTALLATION INSTRUCTIONS WERE SENT TO  
ALL FIELD REPRESENTATIVES.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES  
TO DETERMINE IF THEY HAVE RECEIVED THE ADVISORY LETTER  
FROM OHIO MEDICAL PRODUCTS REGARDING THE NECESSITY  
FOR INSTALLATION OF PRESSURE RELIEF VALVES. ANY

QUESTIONS CONSIGNEES MAY HAVE REGARDING CORRECTIVE  
ACTION SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

LUTZ FERRANDO AND CIA  
FLORIDA 240  
BUENOS AIRES, ARGENTINA

SERVICIO NACIONAL DE SALUD  
SANTIGO, CHILE

CLINICA CENTRAL SA  
SAN ISIDRO 231  
SANTIAGO, CHILE

HOSPITAL NAVAL DE TALCAHUANO  
TALCAHUANO, CHILE

CLINICA PALERMO  
BOGOTA, COLUMBIA

CLINICA CENTRAL DEL  
QUINDIO DE ARMENIA  
QUINDIO, COLOMBIA

DEPARTAMENTO DE CALDAS  
MANIZALES, COLOMBIA

CLINICA EL ROSARIO  
CALLE 62 CRA 41 NO. 62 5  
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PAGE 04 STATE 085278

MEDELLIN, COLOMBIA SA

CLINICA MINERVA SA  
IBAGUE TOLIMA  
COLOMBIA

SERVICIO DE SALUD  
DEL MAGDALENA  
SANTAMARTA, COLOMBIA

INSTITUTO COLOMBIAN  
DE SEGUROS SOCIALES  
AVENIDA 3A NORTE 24 N150  
CALI VALLE, COLOMBIA

COMITE PRO-DAMNIFICADOS  
MANAGUA  
SAN JOSE, COSTA RICA

CLINICA SANTA RITA  
SAN JOSE, COSTA RICA

CLINICA SANTO DOMINGO  
SANTO DOMINGO  
DOMINICAN REPUBLIC

CALMEST C POR A  
AVE TIRADENTES  
APARTADO 169 ZONA 2  
SANTO DOMINGO, DOM. REP.

DEPARTAMENTO MEDICO DEL  
SEGURO SOCIAL ECUATORIANO  
CALLE FLORES NO. 732  
QUITO, ECUADOR

MARCEL J. WOLFF  
CALLE ARCE NO. 1219  
SAN SALVADOR, EL SALVADOR

MINISTERIO DE SALUD  
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PAGE 05 STATE 085278

PUBLICA YAS  
GUATEMALA, GUATEMALA

CELIN PAULEMON  
NO. 54 RUE BONNIE FOI  
PORT AU PRINCE, HAITI

GOBIERNO DE HONDURAS  
HOSP MATERNO INFANTIL  
TEGUCIGALPA, HONDURAS

IRAN BEHDASHT CO. LTD  
P. O. BOX 12-1144  
TEHRAN, IRAN

TEHERAN UNIVERSITY  
BAHRAMI HOSPITAL  
TEHRAN, IRAN

CORALMA SAS

VIA CORSICA 2-1  
POST BOX N-773  
16128 GENOA, ITALY

DONG RUNG MOOLSAN LTD.  
I P O BOX 3022  
SEOUL, KOREA

GOVT REPUBLIC KOREA  
OFFICE OF SUPPLY  
SEOUL, KOREA

ATCO MIDDLE EAST  
P O BOX 5923  
HAMRA ST - ELDORADO BLDG  
BEIRUT, LEBANON

F. MAKHLOUF AND CO.  
144 DAMASCUS AVE.  
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PAGE 06 STATE 085278

P. O. BOX 983  
BEIRUT, LEBANON

REPRESENTACIONES  
MEDICO TECHNICAS SA  
MAZATLAN NO. 83-101  
MEXICO DF MEXICO

ASOCIATION GINECO  
OBSTETRICA HOSP. MEXICO  
MEXICO DF MEXICO

INSTITUTO MEXICANO DEL  
SEGURO SOCIAL  
PASEO DE LA REFORMA 476  
MEXICO DF MEXICO

SECRETARIA DE LA DEFENSA  
NACIONAL  
MEXICO DF  
MEXICO

INSTITUTO DE SEGURIDAD  
SERV SOCIALES DE LOS  
TRABAJADORES DEL ESTADO  
MALPAN DF MEXICO

ALBERTO CASTILLEJO MORAN  
BOGOTA NO. 2383  
GUADALAJARA, MEXICO

HOSPS DE MEXICO  
DR. RUDOLFO STOTOMAYOR  
MEXICO DF MEXICO

ROBERT TERAN G.  
APARTADO 689  
MANAGUA, NICARAGUA

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PAGE 07 STATE 085278

CAJA DE SEGURO SOCIAL  
PANAMA R PANAMA

CLINICAS HOSPITALES  
PANAMA R DE PANAMA

HORACIO ICAZA AND CIA SA  
LA CASA DEL MEDICO  
APARTADO POSTAL 1689  
PANAMA 1, PANAMA

AMERICAN HOSP SUPPLY  
APARTADO 4436  
LIMA, PERU

ASSOCIATED DRUGS INC.  
P.O. BOX 3010  
MANILA, PHILIPPINES

LINOL MARKETING CORP  
188 APO ST.  
QUEZON CITY, PHILIPPINES

BOTICA BOIE, INC.  
P. O. BOX 5081  
(MAKATI P. O. D-711)  
STATE CONDOMINIUM II,  
AGUIRRE ST., LEGASNI VILLAGE  
MAKATI, RIZAL, PHILIPPINES

IUNDINTER INTERCAMBIO  
APARTADO 2761  
LISBON, PORTUGAL

GUIDO RAYOS X  
ALVAREZ QUINTERO

MADRID 4, SPAIN

SANKYO ENTERPRISES LTD.  
P. O. BOX 22059  
TAIPEI, TAIWAN  
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UNCLASSIFIED

PAGE 08 STATE 085278

SHENG TUNG DEVELOP CO.  
P. O. BOX 451  
NO. 44 NEI CHIANG ST.  
TAIPEI, TAIWAN

CESCO LTD.  
P. O. BOX 445  
BANGKOK, THAILAND

HACETTEPE UNIVERSITY  
MEDICAL FACULTY  
ANKARA, TURKEY

COLIMODIO S A  
APARTADO 1053  
CARACAS, VENEZUELA

AMERICAN HOSP SUPPLY  
DE VENEZUELA CA  
APARTADO 50950  
CARACAS 105, VENEZUELA

SISCO

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 08 APR 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1976STATE085278  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M D : AMS  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D760134-0163  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1976/newtext/t19760481/aaaacrfe.tel  
**Line Count:** 366  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 7  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** MartinML  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 10 JUN 2004  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <10 JUN 2004 by SilvaL0>; APPROVED <04 JAN 2005 by MartinML>  
**Review Markings:**  

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Declassified/Released  
US Department of State  
EO Systematic Review  
04 MAY 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - MANDATORY REQUIREMENT FOR INSTALLATION OF RELIEF VALVE IN ALL ANESTHESIA MACHINES  
**TAGS:** OGEN, ETRD, TBIO, TW, TH, TU, AR, VE, CI, CO, CS, DR, EC, ES, FDA  
**To:** BUENOS AIRES  
**MULTIPLE:**  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006